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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/971,960 11/17/97 STILZ

H 026083/0138

EXAMINER

HM12/0514

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DAZIS
ART UNIT

PAPER NUMBER

1616
DATE MAILED:

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05/14/99

**Please find below and/or attached an Office communication concerning this application or
proceeding.**

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/971,960

Applicant(s)

Stilz et al.

Examiner

Sabiha Qazi

Group Art Unit

1616



☒ Responsive to communication(s) filed on Mar 25, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-38 is/are pending in the application.

Of the above, claim(s) 21-24 and 35-38 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 and 25-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 21-24 and 35-38 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Final Action on the Merits

Status of the Application

Applicant request for reconsideration filed in paper no. 10, dated 3/25/99 are entered. Claims 1-38 are pending. Claims 1-20 and 25-34 stand rejected, claims 21-24 and 35-38 are withdrawn from consideration as non-elected invention.

Rejection Withdrawn

Claims rejection under 35 USC § 112 is withdrawn, because applicants amended the definition of W in claim I and arguments are found persuasive.

Rejection Maintained

Claims 1-20, 25, 26, 28, 32, 34, 27, 29, 30, 31, 33, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zoller et al (WO 95/14008), (US Patent 5,424,293), (US Patent 5,554,594) and (CA 123:314540, abstract of DE 4338944). Zoller et al. disclose imidazoline derivatives as inhibitors of platelet aggregation and osteoclast binding to the bone surfaces. In WO 9514008, see formula (I) on page 1 where similar formula is disclosed as instant formula (I); formula (I) in col. 1, where Y

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is $-(CH_2)_m-CO-$, Z is O, W is OH, in US'293; see formula I in col. 1 where Y $-(CH_2)_m-CO-$, Z is O, W is OH in US '594; see formula I in abstract where z is NR, b, c, d and f are 0,1, e, g, and h are 0-6. All the above cited references disclose imidazoleline derivatives as inhibitors of platelet aggregation and metastasizing of carcinomatous cells etc.

Instant claims are obvious over the above cited references when in instant claims Y is C=O, Z is NR, W=C, B is CH₂, e, f are 0, D are CR₂R₃ and E is OH.

2. Claims 1-20, 25, 26, 28, 32, 34, 25, 27, 29, 30, 31, 33, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zoller et al ((CA 123:340969, abstract of WO 95/14008). See formula I, on page I of the reference. See compounds Of RN 170564-97-3 (page 11). Instant compounds can also be homologs of the reference, see compounds of RN 169808-11-1, (page 25), RN 169808-15-5 (page 25) RN 169808-08-6, RN 169808-09-7. These compounds differ from the reference compounds cited above in having methyl groups vs. H.

The prior art of record is drawn to structurally similar compounds which differ from the compounds embraced by the instant claims in that they are homologs. It is recognized in the art

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that homologs are structurally similar and would be expected to possess similar properties. *Ex parte Henze* (POBA 1948) 83 USPQ 167.

Response to Arguments

1. Applicant's arguments filed on 3/25/99 have been fully considered but they are not persuasive. Applicant argue that that "while the prior art's vast genus of possible compounds may encompass some of the presently claimed, the prior art in no way suggests the pharmaceutical activity claimed herein i.e. VLA-4 antagonizing activity, and the resulting end treatments". Examiner respectfully disagree with the arguments.

Note, that applicants are claiming compounds and compositions which are obvious over prior art for reasons setforth in office action mailed in paper no. 6, dated 9/25/98. Case laws cited by the applicants are considered by the examiner but does not apply in the instant case.

There is nothing inventive in a composition of old ingredients of known properties with each ingredient individually as expected. *In re Sussaman*. 58 USPQ 262.

A combination, for the same purpose, of one additive explicitly disclosed in prior art and another suggested by the prior art is at least prima facie obvious. *In re Sussi*, 169

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It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 205 USPQ 1069.

Even if applicant's modification results in great improvement and utility over prior art, it may not be patentable if the modification was within the capabilities of one of the skilled in the art. More particularly, when the general conditions of the claim are disclosed by the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

The claims 1-20, 25-34 have been examined to the extent that they read on the compounds of formula (1), when Z is NR0, Y is C=O, b is 1, c is 1, d is 1, e is 0-6, f is 1, g is 0-6, h is 0-6, E is R1OCO, W is C. This is considered a reasonable search according to MPEP 803.02.

It is suggested that in order to advance prosecution, the non elected subject matter be cancelled when responding to this office action.

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1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

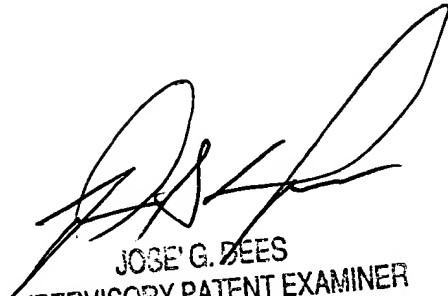
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Sabiha N. Qazi

5/7/99


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616